REMARKS/ARGUMENTS

Telephone Interview

The Applicants thank the Examiner for the courtesy of the telephone interview of September 8, 2009, at which the prior art references were discussed, as well as possible claim amendments. In response to the interview, the Applicants submit the amendments and following remarks.

Office Action

In the Office Action dated May 21, 2009, claims 1 - 5, 7 - 11, 15 - 19, 21 and 22 were rejected under 35 U.S.C. Section 103(a) as unpatentable over Qin, U.S. Patent Publication 2005/0283072 in view of Lin, U.S. Patent 6,068,597, and further in view of Seale U.S. Patent Re. 34,663. Reconsideration of the claims in view of the amendments and the following remarks is respectfully requested.

Amendments

Independent claims 1, 10, and 15 have been amended to clarify that a vibration is induced at the focal point of an ultrasound transducer, that the vibrational velocity of the medium is detected at the focal point of the transducer, and that an elasticity property is determined from the resonance spectrum at the focal point of the transducer. The vibration, detection, and resonance spectrum are therefore all localized at the focal point of the transducer, and within the medium that is characterized.

The Prior Art References

Qin discloses a method for calculating bone mineral density and material strength/stiffness by evaluating propagation of an ultrasound wave through the material tested.

Specifically, an ultrasound wave is directed through a bone specimen from a first transducer 12 to a second transducer 14. (See Fig. 1a; paragraph 46; paragraph 56) A computer 22 calculates propagation times of signals transmitted through the bone, calculates propagation velocity through the bone, and other parameters. (Paragraph 64) These parameters are used in mathematical equations, and particularly in a regression analysis (paragraphs 68 - 80) which relates measured values of the propagation velocity to stiffness, and particularly to bulk modulus, which is a measure of a substance's resistance to compression.

Lin discloses a system which uses audio transducers to induce a large, global vibration. Specifically, in this system, a variable frequency tone generator 124 produces a waveform, which is provided to a pair of audio transducers 112. These audio transducers induce vibrations into a medium or tissue to be scanned (Col. 4, lines 52 - 60), at frequencies distributed between 10 and 350 Hz (Col. 4, lines 66 - 67). This vibrational force is generated by the first order, linear effect of the <u>acoustic</u> transducers. A first order force is a relatively large force, and therefore extends globally through the medium, vibrating the entire object. Ultrasonic Doppler spectrometry is then used to produce a vibrational resonance spectra of tissues.

After a vibration is induced, an ultrasound transducer produces ultrasonic waves which are directed within the medium, and Doppler signal processing is used to detect frequency shifts in the returning echoes. A spectrometer examines the Doppler amplitude variation as a function of the stimulus frequency, and provides a vibrational resonance spectral "signature" curve for the material or tissue being imaged. (Col. 5 lines 47 - 49) Because the applied force is "global", the resonance spectrum is affected by both the material properties and the geometry (shape and size) of the material. As seen by reference to Figs. 6 and 9, because of the complications of the

geometry of the material, the resultant resonance spectrum is a "multi-peak" resonance spectrum (Col. 7, lines 5 - 11). The influence of the geometry of the object cannot be separated from the material properties. Therefore, although this method can provide a qualitative mapping of tissue, e.g. detect and differentiating tumors (Abstract), this method does not and cannot be used to provide a quantitative (absolute) measurement of shear modulus.

Seale, similarly, discloses a system in which a vibration is induced by a mechanical vibration driver (Column 8 line 3 to line 58; Column 12 line 56 to Column 14 line 6). Vibration induced by a mechanical driver is global and the resultant spectrum is similar to that produced by Lin. As a result, a complicated mathematical analysis (such as Network Algorithm, Simulation Algorithm, or Analysis Function Fit Algorithm) is necessary to make any determination as to material properties (Column 2, line 10 to 61). In addition, parameters of the driver (such as its vibrational velocity or force) need to be measured in order to inversely solve for material properties (Column 3, line 20 to 22; claim 1).

<u>Independent Claim 1</u>

Independent claim 1, as amended, recites directing an ultrasound wave in a viscous medium, and modulating the ultrasound wave at a frequency of vibration to produce a vibrational force on the medium <u>at a focal point of the transducer</u>. A vibrational velocity of the medium is determined <u>at the focal point</u> of the transducer and the vibrational velocity is correlated with the frequency of vibration. These steps are repeated for a plurality of frequencies to develop a resonance spectrum of the medium. An elasticity property of the focal point is determined from the resonance spectrum <u>at the focal point of the transducer</u>.

The cited Qin, Lin, and Seale references do not disclose all of the elements of claim 1, either alone or in combination. Specifically, none of the cited references discloses producing a vibrational force in a localized area of a medium to be tested, and determining an elasticity property at the focal point based on resonance spectrum.

Lin discloses the use of ultrasound only to detect vibrations. The ultrasound is not modulated, and does not induce vibrations for resonance characterization, either at the focal point of a transducer or within the medium. Acoustic transducers, rather, are used to induce the vibration in the medium. As discussed above, when acoustic transducers are used to induce a vibration, the vibration is large and extends throughout the object, resulting in a resonance spectrum that includes multiple peaks. This spectrum is substantially different from the spectrum induced in the invention as recited in claim 1, and is not based on velocities detected at the focal point of a transducer.

Seale, as discussed earlier, similarly discloses a global vibration which is then analyzed with complicated mathematical methods. Velocities are not detected at the focal point of a transducer and the resonance spectrum is global rather than local.

Qin discloses directing an ultrasound wave <u>through</u> a bone, and calculating time and velocity parameters of the <u>propagation</u> of the wave through the bone. Qin fails to disclose producing <u>any</u> vibrational force, and, in fact fails to discuss any vibration.

None of the cited references, therefore, discloses detecting a velocity of vibration at the focal point of the transducer or determining an elasticity property of the tissue from the resonance spectrum at the focal point of the transducer. Qin, as discussed above, does not induce a vibration, and does not produce a resonance spectrum at all. Lin produces a multi-peak

resonance spectrum based on Doppler shift data, and uses this spectrum to reconstruct an image. Lin does not correlate a resonance spectrum with an elasticity parameter. Seale similarly induces a global vibration which is then analyzed mathematically.

The cited references, therefore, do not disclose all of the elements of claim 1, either alone or in combination, and the Applicants respectfully request that the rejection of claim 1 and associated dependent claims be withdrawn.

Claims Depending from Claim 1.

Dependent claims 2 - 9 and 22 include all of the limitations of claim 1 and are therefore patentable over the cited references for the reasons set forth above. In addition, these claims recite additional limitations which are not found in the prior art as set forth below.

Claim 2 further recites that the step of modulating the ultrasound wave comprises modulating an amplitude of the ultrasound wave. Neither of the prior art references disclose modulating an amplitude of a focused ultrasound wave, and claim 2 is believed patentable over the cited reference for this reason as well.

Claim 5 further recites the step of comparing a resonance spectrum to a stored resonance spectrum to determine the elasticity property. Again, the prior art references neither teach nor suggest such a step.

Claim 22 recites the step of varying the frequency at which the ultrasound wave is modulated in a range between zero and eight kilohertz. Again, the cited references do not modulate an ultrasound wave, and therefore cannot modulate the wave within this range of frequencies.

In view of the distinctions cited, therefore, claims 1 - 9 and 22 are not obvious in view of the cited references, and the Applicants respectfully request that the rejection of these claims be withdrawn.

Independent Claim 10

Independent claim 10, as amended, recites directing an ultrasound wave modulated at a first oscillating frequency at a focal point at the transducer in the tissue, measuring a vibrational velocity of the tissue at the focal point of the transducer, and varying the oscillating frequency over a range selected to produce a resonant frequency response in the tissue. The resonant spectrum is then correlated to a known elasticity parameter.

Again, none of the cited references discloses the use of an ultrasound wave that is modulated to induce a vibration in tissue at the focal point of the transducer, or discusses a vibrational velocity at the focal point. Qin, as discussed above, does not disclose a frequency vibration for resonance characterization at all. Lin uses an acoustic transducer to induce a vibration, and this vibration therefore is not induced at a focal point of an ultrasound transducer. Seale, similarly, induces a global vibration by a mechanical driver applied at the body surface.

None of the cited references therefore discloses inducing the vibration at a specific focal point, or discloses a method which renders this possible. Qin, again, fails to induce a vibration at all. Lin employs multiple audio transducers which are directed at a medium to be studied. These transducers are directed at the medium in general, and induce a global vibration which is affected by both the size and shape of the medium, as well as the material properties. Seale similarly induces a global vibration. Therefore, elasticity parameters mathematically localized in the medium cannot be easily determined using this method. Rather, significant analysis is required.

None of the cited references, furthermore, discloses quantitatively correlating a resonant spectrum with a known elasticity parameter. Qin, as discussed above, does not determine a resonant spectrum at all. Lin produces a characteristic curve which can include a number of resonant frequencies, and uses this data to produce images. Seale applies a complicated mathematical analysis.

Claim 10, therefore, cannot be obvious in view of the cited references, and the applicants respectfully request that the rejection of claim 10 and associated dependent claims be withdrawn.

Claims Depending from Claim 10

Dependent claims 11 - 14 and 23 include all of the limitations of claim 10 and are therefore patentable over the cited references for the reasons set forth above. In addition, these claims recite additional limitations which are not found in the prior art as set forth below.

Claim 14, as amended, recites the step of varying the oscillating frequency in a range between zero and eight kilohertz. Again, the cited references do not disclose any method of modulating an ultrasound wave, and cannot disclose modulating the wave within this frequency range.

In view of the distinctions cited, therefore, claims 10 - 14 and 23 are not obvious in view of the cited references, and the Applicants respectfully request that the rejection of these claims be withdrawn.

Independent Claim 15

Claim 15 is directed to an apparatus for determining an elasticity property of a viscous medium. The apparatus comprises an ultrasound transducer for applying an ultrasound beam modulated at a selectively varying frequency at the viscous medium, at the focal point of the

transducer, and a detector for measuring a velocity and a frequency of vibration of the medium at the focal point of the ultrasound transducer. A processing unit drives the ultrasound transducer at varying vibration frequencies over a selected frequency range, receives the velocity and frequency of vibration from the detector; and determines a resonant spectrum at selected positions within the medium. The processing unit determines a shear elasticity or a shear viscosity from the resonance spectrum.

As discussed above, none of the cited references discloses the use of an ultrasound wave that is modulated to induce a vibration in tissue at the focal point of the transducer. None of the cited references discloses determining an elasticity parameter based on the resonant spectrum at the focal point. As the cited references fail to disclose all of the elements of the claim, claim 15 cannot be obvious in view of the cited references, and the applicants respectfully request that the rejection of claim 15 and associated dependent claims be withdrawn.

Claims Depending from Claim 15

Dependent claims 16 - 19 and 24 include all of the limitations of claim 15 and are therefore patentable over the cited references for the reasons set forth above. In addition, these claims recite additional limitations which are not found in the prior art as set forth below.

Claim 18 recites that the transducer produces an amplitude modulated signal. New claim 24 further recites that the ultrasound wave is modulated in a selected frequency range is in a range between zero and eight kilohertz. Again, the prior art references fail to disclose any method for modulating an ultrasound wave, do not disclose amplitude modulation of an ultrasound wave, or modulation in the frequency range recited in claim 24.

In view of the distinctions cited, therefore, claims 15 - 20 and 24 are not obvious in view of the cited references, and the Applicants respectfully request that the rejection of these claims be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, the Applicants submit that claims 1 - 22 are in condition for allowance, and respectfully request that a notice of allowance fore these claims be issued.

The Commissioner is authorized to charge any fees under 37 CFR § 1.17 that may be due on this application to Deposit Account 17-0055. The Commissioner is also authorized to treat this amendment and any future reply in this matter requiring a petition for an extension of time as incorporating a petition for extension of time for the appropriate length of time as provided by 37 CFR § 136(a)(3).

Respectfully submitted,

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By: /Terri S. Flynn/

Terri S. Flynn
Quarles & Brady LLP
Reg. No. 41,756
Attorney for Applicant
411 East Wisconsin Avenue
Milwaukee, WI 53202-4497
(414) 277-5229